OMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 01N–0135]

Agency Emergency Processing Under OMB Review; Focus Group Study of Radiation Disclosure Statement Options for Foods Treated With Ionizing Radiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is a focus group study of radiation disclosure statement options for foods treated with ionizing radiation.

DATES: Submit written comments on the collection of information by [*insert date 10 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th Street NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION:

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. The information is essential

to FDA's commitment to Congress to finalize, by March 2002, any regulatory changes regarding radiation disclosure statement for foods treated with ionizing radiation. The use of normal PRA clearance procedures would not allow FDA to conduct this study within the next few months so that the results will be available to support in a timely way the ongoing policy development process.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Focus Group Study of Radiation Disclosure Statement Options for Foods Treated With Ionizing Radiation

Under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343), FDA is mandated to ensure that labeling statements be truthful and nonmisleading. In 1986, under section 409 of the act (21 U.S.C. 348), FDA issued regulations to require that the label and labeling of retail packages or displays of foods treated with ionizing radiation include both the radura logo (the international symbol that indicates radiation treatment) and a disclosure statement (either "Treated with radiation" or "Treated by irradiation") in addition to information required by other regulations (21 CFR 179.26(c)(1) and (c)(2)). To gather information to determine if the existing requirements should be changed and how they should be changed, FDA proposes to conduct a series of six focus groups in three separate geographic locations, one of which will be in the Washington, DC area to facilitate the attendance of interested observers from FDA and industry and consumer stakeholders. The focus groups, eight to nine individuals per group, are to be held in April and May 2001. The objectives of the study are to collect information to: (1) Evaluate whether and under what conditions the current labeling requirement is an obstacle to

acceptance of irradiated foods, and (2) determine how other proposed versions of the disclosure statement might have different effects on consumer acceptance. The information will be used by FDA to determine if the existing requirements should be changed and how they should be changed and to fulfill FDA's commitment to Congress to finalize any regulatory changes by March 2002.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Respondents	Total Annual Respondents	Hours per Respondent	Total Hours
54	1	54	1.5	81

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 3/23/01

March 23, 2001.

William Hubbard

William K. Hubbard,
Senior Associate Commissioner for Policy,
Planning,and Legislation.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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